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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/913,707	07/11/00	LANARI C	P02004US0

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EXAMINER	
SHUKLA, R	
ART UNIT	**PAPER NUMBER**
1632	7

DATE MAILED: 09/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/613,707	Applicant(s) LANARI ET AL.	
	Examiner Ram Shukla	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-12 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-12 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1-12 are pending in the instant application.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 7-8, and 11-12, drawn to a non-transgenic mouse mammary adenocarcinoma cell line MC4-L1, a kit comprising the cell line and an *in vitro* method for testing the activity of a hormone, anti-hormone etc. using the cells, classified in class 435, subclass 325.

II. Claims 1-4, 7-8, and 11-12, drawn to a non-transgenic mouse mammary adenocarcinoma cell line MC4-L2, a kit comprising the cell line and an *in vitro* method for testing the activity of a hormone, anti-hormone etc. using the cells, classified in class 435, subclass 325.

III. Claim 1-4, 7-8, and 11-12, drawn to a non-transgenic mouse mammary adenocarcinoma cell line MC4-L3, a kit comprising the cell line and an *in vitro* method for testing the activity of a hormone, anti-hormone etc. using the cells, classified in class 435, subclass 325.

IV. Claim 5-8 and 11-12, drawn to a non-transgenic mouse mammary adenocarcinoma cell line MC7-L1, a kit comprising the cell line and an *in vitro* method for testing the activity of a hormone, anti-hormone etc. using the cells, classified in class 435, subclass 325.

V. Claims 9 and 10, drawn to an *in vivo* method for testing the activity of a hormone, anti-hormone etc. using a non-transgenic mouse mammary adenocarcinoma cell line MC4-L1, classified in class 424, subclass 9.1.

VI. Claims 9 and 10, drawn to an *in vivo* method for testing the activity of a hormone, anti-hormone etc. using a non-transgenic mouse mammary adenocarcinoma cell line MC4-L2, classified in class 424, subclass 9.1.

VII. Claim 9 and 10, drawn to an *in vivo* method for testing the activity of a hormone, anti-hormone etc. using a non-transgenic mouse mammary adenocarcinoma cell line MC4-L3, classified in class 424, subclass 9.1.

VIII. Claim 9 and 10, drawn to an *in vivo* method for testing the activity of a hormone, anti-hormone etc. using a non-transgenic mouse mammary adenocarcinoma cell line MC7-L1, classified in class 424, subclass 9.1.

3. The inventions of groups I-IV encompass the limitations of the claims 1-4, 7-8, and 11-12 . Should any of these groups be elected for prosecution, the invention of claim 1-4, 7-8, and 11-12 would be examined to the extent it encompasses the claimed invention.

4. The inventions of groups V-VIII encompass the limitations of the claims 9 and 10. Should any of these groups be elected for prosecution, the invention of claims 9 and 10 would be examined to the extent it encompasses the claimed invention.

5. Inventions of the groups I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to different cell lines that have different biochemical, physiological and phenotypic characteristics. Although, the cell lines of the groups I-III are all derived from progestin-dependent CC4-HD tumor, they all have different response to hormones, and have different shape and adhesion properties. The cell line of the group IV is derived from a progestin independent C7-HI tumor and therefore, its properties are different from those of the cells of groups I-III (see pages 13-19 of the specification). Accordingly, the inventions of the groups I-IV would require separate and distinct searches in the patent and non-patent literature.

Inventions of the groups V-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to

in vivo methods of testing activity of a hormone, anti-hormone etc. using different cancer cell lines. Since the cell lines used in the methods are patentably different tumors produced in the animals *in vivo* would be different from each other and therefore, the effects of the test compounds would be different in different groups.

Inventions of the groups I-IV are related to the inventions of the groups V-VIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the cell lines of the groups I-IV are used in the methods of the groups V-VIII respectively. These cell lines can be used for testing compounds in *in vitro* methods or for testing compounds in *in vivo* methods. The *in vitro* and *in vivo* methods are materially different processes that use different reactants for practicing the methods, for example, one requires cell culture whereas the other uses an animal. Furthermore, the steps of the two methods would also be different. Therefore, the searches for the inventions of the groups I-VIII would not be co-extensive.

Because these inventions are distinct for the reasons given above and because each invention would require a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicants are advised to submit a clean version of each amended claim (without underlining and bracketing) according to § 1.121(c) and a copy of all the pending/under consideration claims. For instructions, Applicants are referred to http://www.uspto.gov/web/offices/dcom/olia/aipa/index.htm.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen Hauda, can be reached on (703) 305-6608. The fax phone number for this Group is (703) 308-4242. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the Kay Pinkney whose telephone number is (703) 305-3553.

Ram R. Shukla, Ph.D.

RAM R. SHUKLA, PH.D
PATENT EXAMINER